UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/750,990	12/28/2000	Jorn Borch Soe	674509-2028	9458

7590 02/27/2002

THOMAS J. KOWALSKI, Esq
c/o FROMMER LAWRENCE & HAUG LLP
745 Fifth Avenue
New York, NY 10151

EXAMINER	
HENDRICKS, KEITH D	

ART UNIT	PAPER NUMBER
1761	6

DATE MAILED: 02/27/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/750,990	SOE, JORN BORCH	
	Examiner	Art Unit	
	Keith Hendricks	1761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 30-43 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 30-43 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 112

i) The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 30 and 32-43 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the use of lipases and/or esterases, does not reasonably provide enablement for the use of *any* random enzyme. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

A number of factors must be considered in assessing the enablement of an invention, including the following: the breadth of the claims, the amount of experimentation necessary, the guidance provided in the specification, working examples provided, predictability, and the state of the art. See *In re Wands*, 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Circ. 1988).

Applicants have not provided sufficient guidance toward the isolation, production, utilization and functionality of any random various enzyme, of any source (save for instant claim 33) or class of enzyme. The stated limitation of generating an emulsifier from a triglyceride, does not serve to provide sufficient guidance for one skilled in the art to select from the thousands of known enzymes which may or may not act upon the triglyceride in such a manner. The end product of an emulsifier is also such a potentially large set of multiple classes of compounds, that this does not serve to sufficiently limit, and provide guidance for, the selection of the type of enzyme which would function in the instant claims. Applicants have not provided guidelines concerning the proper protocol for selecting such enzymes. Nor have applicants provided working examples -- beyond a limited number of lipases -- as guidance in this matter. Thus, absent these necessary teachings, it would require an undue amount of experimentation for one skilled in the art to randomly and blindly attempt to utilize a non-specified enzyme which, *a priori*, would not be known whether it would function in the claimed system, absent such guidance. Thus, the path to successfully screening and utilizing such, would be highly unpredictable.

ii) The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 30-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

NOTE: This application claims priority to a foreign document. *Applicants' representative is strongly encouraged to review the application, especially the claims, to comply with accepted U.S. Patent structure and language.* The *newly-added* claims are generally narrative and indefinite, failing to conform with current U.S. practice, and are replete with grammatical and idiomatic errors. The rejections under 35 USC 112 2nd paragraph below are an attempt to call attention to these occurrences, yet may not be comprehensive.

- In claim 30, part (i), the term "a" is suggested to be inserted between "containing" and "triglyceride."
- The term "generated", as used in claims 30, 34 and 39, for example, is indefinite. It is unclear if this implies (a) the triglyceride is broken down to produce smaller compounds, including an emulsifier, (b) the action of the enzyme couples the triglyceride with an additional (unspecified) compound, to form an emulsifier, or (c) a combination of both. Each of claims 30, 34 and 39 appear to present different, and possibly conflicting, circumstances to this effect.

- In claim 33, the terms *Penicillium and Pseudomonas* (2nd occurrence), are misspelled.

- Claims 31, 33, 36-38 and 40 recite improper Markush-type claim language, regarding the multiple selections recited therein. Use of either the open-set language "**comprising** A, B, C... **or** D", or closed-set language "**selected from the group consisting of** A, B, C... **and** D", is suggested. Applicant is cautioned against the introduction of new matter in this regard.
- A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949).

  In the present instance, claim 31 recites the broad recitation of "esterase", and the claim also recites a "lipase", which is the narrower statement of the range/limitation. As a lipase *is* an esterase, it is unclear as to what enzymes are intended to be encompassed by the limitation(s) recited.

- In claim 31, it is unclear as to what is encompassed by a "derivative" of one of the enzymes. The metes and bounds of the term are not apparent, and are not clearly set forth in the specification. It is unclear if this refers to (a) simple chemical variations, which may or may not alter the function of the enzymes, (b) functional and non-functional "derivatives", (c) recombinant and/or natural mutations, which are not typically considered to be "derivatives" of enzymes, or (d) another type of "derivative".
- Similarly, it is unclear as to what is encompassed by the term "derivative" as used in claims 36-37.
- The use of parentheses ( ), in the claims, is unnecessary, and creates a situation where it is unclear if the limitations within the parentheses is merely exemplary of the remainder of the claim, and therefore not required, or a required feature of the claims. In claim 36, for example, it may be clear that these are intended to further define the term they follow; however, this is unnecessary, as the original terms are clear and precise in the art.
- On the other hand, in claim 37, not all peptides are "(partly hydrolysed proteins)", and thus the limitations of the claim are unclear. The distinction between "protein hydrolysates", "peptides" and "partly hydrolysed protein", in claim 37, is unclear.
- In claim 37, the term "hydrolysed" should be "hydrolyzed".
- Regarding claims 36 and 38, the term "including" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d). For example, it is unclear if the limitation of claim 38 is all baked goods, or only those specific types recited. It is suggested that either (a) the example limitations following the term "including" be deleted, leaving the classes of claimed components only, or (b) the claims comply with the following example: "... frozen dairy products selected from the group consisting of ice cream and ice milk".
- Similarly, the term "preferably", for example as used in claim 38, is indefinite.
- Claims 36 and 38 are indefinite and confusing in their structure. Initially, the claims recite improper Markush-type language, as explained above, from the first instance of the phrase "is selected from", in the first line. The combined use of these phrases, along with the terms "including" and "preferably", do not clearly set forth the claimed invention.
- In claim 36, it is unclear as to which compounds are encompassed by the phrase "and mixtures thereof", due to the confusing claim language utilized.

- Claim 38 is indefinite, as it is unclear as to how the simple reaction method of claim 30, from which it depends, is to "provide the foodstuff" as recited in claim 38. The starting food materials may comprise triglycerides, and the resultant reaction product may be *incorporated into* a foodstuff (see applicants' instant examples), however, this reaction does not result in, or "provide the foodstuff".
- In claim 38, it is suggested that the abbreviations "w/o" and "o/w" be spelled out to indicate their intended meaning. This would avoid, for example, confusion of whether "w/o" stands for "without", or "water in oil".
- In claim 38, the phrase "margarine shortening and spreads" is indefinite. Initially, it is unclear if this indicates three components (margarine, shortening, and spreads), or two (a margarine shortening component, and spreads).
- The term "spreads", in claim 38, is indefinite. It is unclear as to what types of foodstuffs are encompassed by the term, and what would qualify as a "spread". Further, it is apparent that certain other foodstuffs recited in the claim would be considered "spreads", such as margarine, whipped cream and mayonnaise, and thus this presents a situation similar to that for "enzymes" and "lipases", as discussed above. Thus, in the present instance, claim 38 recites the broad recitation of "spreads", and the claim also recites margarines, whipped cream and mayonnaise, which are the narrower statements of the range/limitation.

- Claim 39 would be more clear if the term "resultant" be added to modify the phrase "the foodstuff" (i.e. to "the resultant foodstuff"). As the claim stands, it appears that the foodstuff would necessarily contain the emulsifier and 'second functional ingredient' prior to the claimed process steps.
- In claim 39, it is unclear for what function the "second functional ingredient" is used. It is unclear if this is a by-product of the reaction, for example, water, and/or if this is a compound which is material to the foodstuff.

- Claim 40 is indefinite for the recitation of "a sugar or a sugar alcohol, more preferably ascorbic acid". It is unclear if these are three choices, or two choices wherein the ascorbic acid is supposed to fall into one of the categories of sugar or sugar alcohol. The latter option does not appear to be accurate, but is unclear from the claim. The phrase "more preferably" renders the

claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claims 42-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that it fails to point out what is included or excluded by the claim language. This claim is an omnibus type claim. The claims themselves must set forth each limitation of applicants' invention to be protected.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

1. Claims 30-43 are rejected under 35 U.S.C. 102(e) as being anticipated by Schneider et al. (WO 92/14830, of record).

Schneider et al. disclose the production of "amphiphilic products such as esters, sugar-esters, peptide-esters... glycoproteins", as well as "the pure precipitation of 1-monoglycerides". Hydrophilic substrates such as glucose, sugar-alcohols, and amino acids, are reacted with substrates such as triglycerides. "The method is also applied to enzymatic reactions with saccharides and polyalcohols" (abstract). The enzymes used include lipases from *Mucor miehei* (*Rhizomucor miehei* is also known and classified in the art as *Mucor miehei)*, *Psuedomonas fluorescens, Rhizopus delemar, Candida cylindracea,* and *Penicillium cyclopium*. "The enzyme is removed by filtration", thus inactivating it (pg. 28). Note that the instantly-claimed list of resultant foodstuffs produced includes "edible oils and fats" (claim 38). As the method steps are the same as those instantly claimed, and the claim limitations

encompass the teachings of the reference, it would be expected that the same enzymatic reaction(s) would yield "an emulsifier" compound, as well as a by-product secondary compound(s).

2. Claims 30-32,34-36, 38-39 and 41-43 are rejected under 35 U.S.C. 102(b) as being anticipated by Van Den Ouweland et al. (US PAT 5,695,802, of record).

Van Den Ouweland et al. disclose the hydrolysis of triglycerides in fat-containing materials such as butter and oil, with water and a lipase from various microbes, including *Candida, Rhizopus, Mucor, Penicillium, Aspergillus, Pseudomonas flourescens* (example 4), and *Mucor*. In the example 3, the butter was "heated for 15 minutes at 90^0 C to stop the hydrolysis". The reaction produced monoglycerides (col. 1), and further, "the hydrolysate thus obtained can be used as such, or it can be emulsified to form a homogeneous paste" (col. 4, lines 57-58). As the method steps are the same as those instantly claimed, and the claim limitations encompass the teachings of the reference, it would be expected that the same enzymatic reaction(s) would yield "an emulsifier" compound, as well as a by-product secondary compound(s).

3. Claims 30-43 are rejected under 35 U.S.C. 102(e) as being anticipated by Michelsen et al. (US PAT 6,143,543)

Michelsen et al. provides an enzyme system comprising a ferulic acid esterase (FAE) from *Aspergillus niger*, which "can improve food and feed and the preparation of food and feed" (col. 2). The reference specifically demonstrates the use of the esterase upon plant material, such as wheat (bran, or water insoluble pentosans), sugar beets, and corn. Further, the enzyme is used within a method to form a dough and bakery products (col. 5. See also examples G-H.). At col. 7, lines 44-47, it is stated that the enzyme substrates may include polysaccharide-based substrates such as xylan and pectin, as well as "glyceride oligomers". Example G demonstrates the use of the enzyme, with water, upon wheat bran, whereupon completion, the reaction was stopped by freeze drying, thus inactivating the enzyme.

Wheat naturally contains various glyceride compounds, including triglycerides. Wheat also contains various mono- and poly-saccharides, i.e. sugars, such as xylose, glucose, fructose. Similarly, corn naturally contains triglycerides (for example, in corn oil) and sugars (for example, corn syrup), as well. Thus, the reference teaches the addition of an *Aspergillus niger* esterase to "a food material containing a triglyceride". As the method steps are the same as those instantly claimed, and the claim limitations encompass the teachings of the reference, it would be expected that the same enzymatic reaction(s) would yield "an emulsifier" compound, as well as a by-product secondary compound(s).

4. Claims 30-36, 38-39 and 41-43 are rejected under 35 U.S.C. 102(b) as being anticipated by either of Moore et al. (EP 0 652 289, of record) or McNeill et al. (EP 0445 692, of record).

Moore et al. disclose the hydrolysis of triglycerides in the presence of diglycerides and water, to yield randomly-interesterified triglycerides, as well as diglycerides, and monoglycerides (col. 6), by using the lipase from *Mucor miehei*. Note that *Rhizomucor miehei* is also known and classified in the art as *Mucor miehei*. "Hydrochloric acid is then added to stop the action of the enzyme" (col. 6, lines 20-21). Note that the instantly-claimed list of resultant foodstuffs produced includes "edible oils and fats" (claim 38). As the method steps are the same as those instantly claimed, and the claim limitations encompass the teachings of the reference, it would be expected that the same enzymatic reaction(s) would yield "an emulsifier" compound, as well as a by-product secondary compound(s).

McNeill et al. disclose the production of a monoglyceride as an emulsifying agent (pg 6) from reacting fat and oil (containing triglycerides) and glycerol, in water, with a lipase from *Chromobacterium viscosum, Psuedomonas fluorescens,* or *Mucor miehei*. Note that *Rhizomucor miehei* is also known and classified as *Mucor miehei*. Note that the instantly-claimed list of resultant foodstuffs produced includes "edible oils and fats" (claim 38).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keith Hendricks whose telephone number is (703) 308-2959. The examiner can normally be reached on M-F (8:30am-6pm); First Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Milton Cano can be reached on (703) 308-3959. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3602 for regular communications and (703) 872-9565 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

KEITH HENDRICKS
PRIMARY EXAMINER